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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KISH, JAMES M	

ART UNIT	PAPER NUMBER
3737	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/688,801	SOLAR ET AL.	
	Examiner	Art Unit	
	James Kish	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8-70 and 76-103* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *76-90 and 94-103* is/are allowed.

6)☒ Claim(s) *1-5,8,9,12-21,23,24,31-35,37-48,50,51,58-63 and 67* is/are rejected.

7)☒ Claim(s) *10,11,22,25-30,36,49,52-57,64-66 and 68-70* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/22/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-70 have been considered but are moot in view of the new ground(s) of rejection.

With respect to Applicant's argument that the combination of Allen in view of Vilsmeier would cause Allen to be inoperable, the Examiner respectfully disagrees in view of tertiary teaching reference Kraus (US Patent No. 3,918,440). Allen provides a fiducial implant for the human body that is detectable by imaging systems comprising a spherical head with a bone screw shaft portion. The spherical head comprises an inlet shaped for engagement by an allen wrench. Vilsmeier provides a spherical fiducial head with a conical divot removed to provide access to the center of the sphere for a positioning instrument. The Applicant argues that the combination would render Allen inoperable in that there would be no means provided for rotating the bone screw shaft because the conical divot would remove the inlet for the allen wrench. Kraus teaches a bone screw with a substantially spherical head portion and a bone screw shaft. The head is provided with an inlet for engagement with an allen wrench type screwdriver. At the base of the inlet is provided a conical receptacle that provides a point located at the center of the circular head portion when viewed in the axial direction. Kraus teaches a apparatus that incorporates the structural limitations necessary to combine Allen with Vilsmeier.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1- 5, 12-13, 15, 17, 21, 23-24, 32-35, 40-41, 44, 48 and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen (US Patent No. 5,397,329) in view of Kraus (US Patent No. 3,918,440). Allen discloses a fiducial implant for the human body that is detectable by imaging systems (see Abstract). A first portion 12 has at least a portion which is spherical and defines a surface for cooperating with a tool for securing the second portion 14 to the bone (column 5, lines 1-19). This first portion is preferably hollow and can be filled with a gel having various desired dopants, depending on the imaging system (column 7, lines 32-39). Preferably, the anchor should be screwed into the bone, rather than driven with an impact tool to lessen the chance of fracturing the bone (column 7, lines 40-52). However, Figure 1a shows an embodiment wherein second portion 14 is not threaded and would need to be driven into the bone by a means other than screwing. Where anchor is a screw, preferably an indentation in the shape of a polygon recess to receive an allen wrench is located in marker 12. Where anchor is not a screw, the marker is self-tapping (Figure 1a). The use of an allen wrench is due to the increased symmetrical integrity provided over the use of the cross shaped receptor site for a Phillips screw driver or a single groove receptor site for a standard screw driver (column 7, lines 53-61). However, if

this symmetry was not important, it would be obvious to use one of these other screwdriver shapes. A trocar is placed at the anchoring site and the marker is placed within the trocar, thereby providing a guide collar about the marker (column 8, lines 1-9). Allen discloses registering an external coordinate system B of a robotic arm with an internal coordinate system A. This is accomplished by touching the tip of the robotic arm on the fiducial implant (column14, lines 28-53). However, Allen does not teach a conical divot to provide access to the center of the head portion. An alternative arrangement for a bone screw type device is taught by Kraus. As illustrated in Figure 4, the head portion comprises an slot for engagement with the tip of an allen wrench **25** to enable driving of the screw into bone. At the base of the slot is provided a conical receptacle that provides a point located at the center of the circular head portion when viewed in the axial direction. In addition to this conical portion, the is a conically shape chamfer edge at both sides of the allen wrench engagement portions. As can be seen in Figure 3, there is a cap that can be placed and locked into the bone screw head, making the substantially spherical shaped head entirely spherical. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the arrangement as taught by Kraus with the marker of Allen to provide a cover to fit over the allen wrench engagement portion once the screw is in place.

Claims 1, 8-9, 14, 16, 19-20, 32, 41-43, 46-47, 59-63 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen in view of Vilsmeier (US Patent No. 6,351,659), and further in view of Kraus. Allen discloses a fiducial implant for the

human body that is detectable by imaging systems (see Abstract). A first portion 12 has at least a portion, which is spherical and defines a surface for cooperating with a tool for securing the second portion 14 to the bone (column 5, lines 1-19). This first portion is preferably hollow and can be filled with a gel having various desired dopants, depending on the imaging system (column 7, lines 32-39). Preferably, the anchor should be screwed into the bone, rather than driven with an impact tool to lessen the chance of fracturing the bone (column 7, lines 40-52). However, Figure 1a shows an embodiment wherein second portion 14 is not threaded and would need to be driven into the bone by a means other than screwing. Where anchor is a screw, preferably an indentation in the shape of a polygon recess to receive an allen wrench is located in marker 12. The use of an allen wrench is due to the increased symmetrical integrity provided over the use of the cross shaped receptor site for a Phillips screw driver or a single groove receptor site for a standard screw driver (column 7, lines 53-61). However, if this symmetry was not important, it would be obvious to use one of these other screwdriver shapes. A trocar is placed at the anchoring site and the marker is placed within the trocar, thereby providing a guide collar about the marker (column 8, lines 1-9). Allen discloses registering an external coordinate system B of a robotic arm with an internal coordinate system A. This is accomplished by touching the tip of the robotic arm on the fiducial implant (column14, lines 28-53). While Allen discloses a divot in the top of the marker portion 12, it is not described as a divot for placement of a localization instrument. Vilsmeier teaches a localization system with markers that facilitates easy localization by a computer/camera unit. The system has spherical

markers provided with a reflective coating (column 4, lines 24-28). Furthermore, a "funnel configuration" is used to access precisely the center point of the landmark with a point. Due to the landmark's funnel configuration they can be localized even after they are covered by a cloth. See column 7, lines 20-47, as well as Figure 8. Also, column 12, lines 1-11 teach the ease of sterilization of the markers. Once the markers have been sterilized they would obviously have a coating of sterilizing agent. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a funnel configuration, as taught by Vilsmeier, in the fiducial system of Allen because Allen states that it is very important to locate the exact center of the marker (column 6, lines 61-68). However, there is no means provided for locating the exact center with the localization system. Vilsmeier states that the funnel configuration allows the surgeon to access precisely the center point of the landmark with the pointer (column 7, lines 20-47). Kraus teaches a bone screw with a substantially spherical head portion and a bone screw shaft. The head is provided with an inlet for engagement with an allen wrench type screwdriver. At the base of the inlet is provided a conical receptacle that provides a point located at the center of the circular head portion when viewed in the axial direction. Kraus teaches a apparatus that incorporates the structural limitations necessary to combine Allen with Vilsmeier. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use Kraus as a teaching reference to incorporate the center point localization of a spherical marker head, as taught by Vilsmeier, while also allowing an allen wrench to fix the screw into the bone, as taught by Allen. Furthermore, Kraus provides a cap that

protects the inside of the slot and provides a fully spherical marker head, preventing it from catching and causing discomfort to the patient.

Claims 18, 37-39, 45 and 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen in view of Kraus, further in view of any one of Reed (US Patent No. 5,968,047). Allen in view of Kraus is described above. However, these bone screw portions do not provide an unthreaded portion. Reed discloses a sterile fixation device with a threaded portion and an unthreaded portion with an aperture, or groove **112** (*see* Figure 23). This device is made completely sterile. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a threaded and unthreaded portion as taught by Reed, as well as create a sterile bone fixation device in order to create an immunologically acceptable joint with the bone (column 2, lines54-55).

Claims 31 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen in view of Vilsmeier and Kraus, further in view of Franck et al. (US Patent No. 6,273,896). Allen in combination with Vilsmeier and Kraus is described in the above rejection. However, none of these references clearly teaches a headband. Franck teaches as an alternative to implanting markers to instead use an elastic headband to place them. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a cap to place on the head of the bone

screw/fiducials of Allen, Vilsmeier and Kraus in order provide an alternative method of placing the markers that is less invasive for the patient.

Allowable Subject Matter

Claims 76-90 and 94-103 allowed.

Claims 10-11, 22, 25-30, 36, 49, 52-57, 64-66, 68-70 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Also see Item **22** Figures of Grimm et al. (US Patent App. No. 2004/0122305).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Kish whose telephone number is 571-272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMK

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER